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DIACEREIN IN OSTEOARTHRITIS - RESULTS OF A POSTMARKETING SURVEILLANCE PROJECT

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Aim of Study: Diacerein is a symptomatic slow acting drug in osteoarthritis (SYSADOA) and there is substantial evidence in the literature about its efficacy and tolerability. The main objective of this Austrian postmarketing surveillance project was to provide quantitative data about diacerein performance under practical conditions in patients suffering from osteoarthritis (OA).
Methods: The study design was a prospective, open, longitudinal patient collective observation over a period of 6 months with monthly visits. Efficacy variables were joint pain at rest and on movement measured on a 100-mm visual analogue scale (VAS) and global assessment of quality of life by the patient and physician (Likert scale). Safety was assessed by types and frequencies of adverse events. An exploratory evaluation strategy based on the intention to treat principle was performed. Intraindividual comparisons were based on the non-parametric sign test using the two-sided 5% level of statistical significance.
Results: 310 patients, diagnosed with OA of different joints, were recruited into this study (average age 62 years, 60% women). The study was conducted from July 2004 to July 2005 in the practices of 56 Austrian physicians. There were 76% of patients pretreated and the median pretreatment duration was 1.3 years. A total of 67% of the patients had OA of the knee, 29% of the hip, 25% of the fingers and 39% of other joints. It was possible to collect data over the 6-month treatment period for 60% of the patients.
VAS pain at rest and on movement and quality of life assessments by the patient and physician showed statistically significant improvements ($p<0.001$) as compared to baseline from Month 1 onwards. Gastrointestinal disorders were the main adverse events reported; they were generally mild to moderate and of transient nature, and only occasionally led to premature diacerein discontinuation.
Conclusion: It is acknowledged that clinical studies have a high degree of internal validity but also widely lack patient population representativity. Therefore, data from clinical practice are essential for making informed therapeutic decisions.
Complete data could be gathered for only 60% of the patients. This may be related to the fact that the product is not reimbursed by the Austrian social security system. Therefore, patients and physicians had to either make substantial efforts to achieve exceptional social security coverage, have an additional private health insurance or pay by themselves.
The results of this study indicate a significant symptomatic efficacy and a good tolerability of diacerein. This suggests that diacerein has a positive benefit/risk ratio in a clinical setting. In summary, the results are in line with the currently published data on diacerein.

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PREDICTIVE FACTORS OF THE EFFICACY OF VISCOSUPPLEMENTATION WITH NON ANIMAL STABILIZED HYALURONIC ACID IN PATIENTS WITH HIP OSTEOARTHRITIS

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Rationale: Non Animal Stabilized Hyaluronic Acid (NASHA) has been suggested to be effective for treating symptoms of patients suffering from hip osteoarthritis (OA)
Aim: To determine the predictive factors of long term efficacy of viscosupplementation by NASHA in patients with symptomatic hip OA.
Methods: Open prospective trial. Patients: Thirty patients suffering from hip OA. Methods: Intra articular injection of NASHA (3ml) in the hip under fluoroscopy. Follow-up visits at day 7-30-60-90-180. Evaluation: Walking pain on 100 mm VAS, WOMAC index, patient's global assessment; Lequesne index; Non steroidal anti inflammatory drugs (NSAIDs) and analgesics consumption. Efficacy was assessed by comparing the mean variation of the outcome variables to that defining the Minimal Clinically Important Improvement (MCII), and by comparing the end-point values to that determining the Patient Acceptable Symptom State (PASS +). *Statistics:* Intent-to-treat analysis. Predictive factors for response were studied using logistic regression analysis.
Results: The mean decrease of all the outcome variables was higher than MCII. Patients who were responsive to treatment (PASS+) were characterized at baseline by a lower level of pain and disability (pain, patient's assessment, WOMAC Lequesne index respectively 45.6, 44.6, 30 and 8.2) than PASS - patients (60.7, 62.3, 50 and 10), and by a shorter disease duration (30 vs 79 months). The result at D30 was highly predictive of the result at D180 ($P<0.002$).
Conclusion: The present data suggest that a single intra-articular injection of NASHA is effective to relieve durably pain in patients suffering from hip OA, particularly in those with moderate condition.

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ARTHROSCOPIC DEBRIDEMENT FOR OSTEOARTHRITIS OF THE KNEE

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Aim: The role of arthroscopy in osteoarthritis (OA) of the knee remains to be defined and few clinical and radiographic characteristics have been quantitatively associated with outcome. The hypothesis of this study is that outcome after arthroscopic debridement for OA of the knee is associated with preoperative clinical and radiographic features and intraoperative characteristics and that subsets of patients exist that are more and less likely to respond favorably.

Abstract P173 – Table 1

Outcome measures	Baseline median (mm)	End-point median (mm)	variation mm (%)	p	PASS mm	MCII mm (%)
Walking pain	53.6	34	-19.6(-36.6)	0.04	35.0	-15.3(-32)
Patient's assessment	51.1	27.5	-23.6(-46.2)	0.004	34.6	-15.2(-32.6)
WOMAC	40.0	30.4	-9.6(-23.5)	ns	34.4	-7.9(-21)
Lequesne index	9.1	6.1	-3(-33.3)	0.05	na	na